



Express Mail No. EV473970934US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Curtis Wright, IV	Confirmation No.:	2381
Serial No.:	10/690,384	Art Unit:	1615
Filed:	October 20, 2003	Examiner:	Mercier, Melissa S.
For:	TITRATABLE DOSAGE TRANSDERMAL DELIVERY SYSTEM	Attorney Docket No.:	6750-237-999
		CAM No.:	305158-999235

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In accordance with the duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

- 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
- 1b. A legible copy of:
- ☐ Each publication or that portion which caused it to be listed on the PTO-1449;
 - ☐ For each cited pending unpublished U.S. application, the application specification including the claims, and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion that have been checked to be unavailable at the USPTO's private PAIR system;
 - ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report;
 - ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications;
 - ☐ All other information or portion which caused it to be listed on the PTO-1449.
- 1c. ☒ Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and U.S. patent application publications are not submitted herewith unless required by the office.
- 1d. ☐ Pursuant to 1287 OG 163, copies of cited pending unpublished applications that are available at the USPTO's private PAIR system are not submitted herewith.

2. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
 - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
 - ☒ Before the mailing of the first Office action on the merits;
 - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

(Check either Item 3a or 3b)

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☐ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed.
 - ☐ to be charged to Jones Day Deposit Account No. 50-3013.

(Item 3b to be checked if any reference known for more than 3 months)

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
 - ☐ to be charged to Jones Day Deposit Account No. 50-3013.
5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked):

(Check either Item 5a or 5b)

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not

received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☒ This application is a continuation application under 37 C.F.R. §1.53(b) or (d).

(Check appropriate Items 6a, 6b and/or 6c)

6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

6b. ☒ Copies of publications listed on Form PTO-1449 from prior application Serial No. 09/714,604, filed on November 16, 2000, of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).

6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.

7. ☐ This is a Supplemental Information Disclosure Statement. (Check Item 7a)

7a. ☐ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on . A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on .

8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

(Check Item 8a, 8b, or 8c)

8a. ☐ Satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.

8b. ☐ Set forth in the application.

8c. ☐ Enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.

10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: April 3, 2007


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Enclosure



Express Mail No.: EV473970934US

Sheet 1 of 3

LIST OF REFERENCES CITED BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.

6750-237-999

APPLICATION NO.

10/690,384

APPLICANT

Curtis Wright, IV

FILING DATE

October 20, 2003

ART UNIT

1615

U.S. PATENT DOCUMENTS

* Examiner Initials	Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A01 4,573,996	3/4/86	Kwiatk et al.	
	A02 4,597,961	7/1/86	Etscom	
	A03 4,666,441	5/19/87	Audriola et al.	
	A04 4,781,924	11/1/88	Lee et al.	
	A05 4,788,064	11/29/88	Patel et al.	
	A06 4,806,341	2/21/89	Chien	
	A07 4,837,027	6/6/89	Lee et al.	
	A08 4,839,174	6/13/89	Baker et al.	
	A09 4,840,796	6/20/89	Sweet et al.	
	A10 4,906,169	3/6/90	Chien et al.	
	A11 4,908,213	3/13/90	Govil et al.	
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	A13 5,023,084	6/11/91	Chien et al.	
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	A15 5,120,546	6/9/92	Hansen et al.	
	A16 5,163,899	11/17/92	Sibalis	
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	A18 5,560,922	10/1/96	Chien et al.	
	A19 5,676,373	10/14/97	Sakai et al.	
	A20 5,676,969	10/14/97	Wick et al.	
	A21 5,686,112	11/11/97	Liedtke	
	A22 5,736,154	4/7/98	Fuisz	
	A23 5,879,701	3/9/99	Audett et al.	
	A24 5,902,603	5/11/99	Chen et al.	
	A25 5,919,477	7/6/99	Bevan et al.	
	A26 5,968,547	10/19/99	Reder	
	A27 6,007,837	12/28/99	Enscore et al.	
	A28 6,010,715	1/4/00	Wick et al.	
	A29 6,018,092	1/25/00	Dunshee	
	A30 6,143,320	11/7/00	Becher et al.	

FOREIGN PATENT DOCUMENTS

*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
	B01	EP 0 559 411 A1	09/08/92	EPO		
	B02	DE 199 00 645 A1	07/13/00	Germany (with English Abstract)		
	B03	EP 0 298 297 A1	11/19/91	EPO (with English Abstract)		
	B04					
	B05					
	B06					
	B07					
	B08					
	B09					
	B10					
	B11					
	B12					

NON PATENT LITERATURE DOCUMENTS

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C01	Carroll, "Estrogen patch may be safer for heart than pill," Reuters Health, April 2003	
	C02	Edinboro et al., 1997, "Fatal fentanyl intoxication following excessive transdermal application", J Forensic Sci. Jul;42(4):741-3	
	C03	Jeal W. & Benfield P., 1997, "Transdermal Fentanyl. A Review of its Pharmacological Properties and Therapeutic Efficacy in Pain Control", Drugs, 53(1):109-138	
	C03	Jordan WP Jr., 1997, "Allergy and topical irritation associated with transdermal testosterone administration: a comparison of scrotal and nonscrotal transdermal systems", Am J Contact Dermat. 8(2):108-13.	
	C05	Jordan et al., 1998, "Comparison of the skin irritation potential of two testosterone transdermal systems: an investigational system and a marketed product", Clin Ther. 20(1):80-7	
	C06	Kemp et al., 1997, "Postmortem Distribution of Nicotine and Cotinine From a Case Involving the Simultaneous Administration of Multiple Nicotine Transdermal Systems", J. Anal. Toxicol. 21(4):310-313	
	C07	Korte et al., 1996, "Day-to-day titration to initiate transdermal fentanyl in patients with cancer pain: short- and long-term experiences in a prospective study of 39 patients", J Pain Symptom Manage. 11(3):139-46	
	C08	Mahmood I., 1997, "Clinical pharmacokinetics and pharmacodynamics of selegiline. An update", Clin Pharmacokinet. 33(2):91-102. Review.	
	C09	Manitz et al., 1998, "On Mathematical Modeling of Dermal and Transdermal Drug Delivery", J. Pharm. Sci. 87(7):873-879	
	C10	Meikle et al., 1996, "Pharmacokinetics and metabolism of a permeation-enhanced testosterone transdermal system in hypogonadal men: influence of application site- a clinical research center study", J Clin Endocrinol Metab. 81(5):1832-40	
	C11	Meikle et al., 1992, "Enhanced transdermal delivery of testosterone across nonscrotal skin produces physiological concentrations of testosterone and its metabolites in hypogonadal men", J Clin Endocrinol Metab. 74(3):623-8.	
	C12	Popli S et al., 1983, "Transdermal clonidine for hypertensive patients", Clin Ther. 5(6):624-8.	
	C13	Riley S et al., 1992, "Comparison of two transdermal nitroglycerin systems: Transderm-Nitro and Nitro-Dur.", Clin Ther. 14(3):438-45	
	C14	Southam M.A., 1995, "Transdermal Fentanyl Therapy: System Design, Pharmacokinetics and Efficacy", Anti-cancer Drugs 6 Suppl. 3: 29-34	
	C15	Van Buskirk et al., 1997, "Scale-up Adhesive Transdermal Drug Delivery Systems", Pharm. Res. 14(7):848-852	

NY1-3978716v1

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

NON PATENT LITERATURE DOCUMENTS

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C16	Wang et al., 2000, "Pharmacokinetics of transdermal testosterone gel in hypogonadal men: application of gel at one site versus four sites: a General Clinical Research Center Study", J Clin Endocrinol Metab. 85(3):964-9.	
	C17	Woolf et al., 1996, "Self-poisoning among Adults Using Multiple Transdermal Nicotine Patches", J. Toxicol. Clin. Toxicol. 34(6):691-8	

NVI-3978716v1

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<p>*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.</p>	